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TITLE: Alaska Native Parkinson's Disease Registry

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

This registry initiates a program of epidemiological assessments of PS among Alaska Natives to study the natural history and clinical management of PS, and establishes a database of Alaska native people with PS for public health, research and educational purposes. As feasible, the prevalence of PS in Alaska Natives may be estimated as well. This registry not only would facilitate future research into PS etiology, but also guide health care planning and community education efforts in this population. The proposal takes advantage of a case control study of PS that is commencing in the same population. The registry is designed in two phases. Phase 1 is a developmental period and is well underway at this time. During this phase, we are establishing the data collection and dissemination protocols, regulatory submissions are under review for the registry to obtained necessary approvals, the registry database is under development and a pilot project in Anchorage will be initiated pending approvals. Phase 2 has not yet begun. It is a period of educational outreach and active statewide data collection on prevalent and incident cases of PS. After Phase 2 ends, the registry will be sustained through the Alaska Native Medical Center.

15. SUBJECT TERMS
Alaska Native; Parkinson's disease; Registry; Etiology; Epidemiology; Ascertainment

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A. Introduction

Parkinsonism (PS) is a syndrome characterized by tremor, rigidity, slowness of movement, and problems with walking and balance. Parkinson's disease is the most common form of PS, accounting for about 1% of the U.S. population over age 50 years. Little information is available about trends in PS, particularly in Alaska Natives.

This registry initiates a program of epidemiological assessments of PS among Alaska native people to study the natural history and clinical management of PS, and establishes a database of Alaska native people with PS for public health, research and educational purposes. As feasible, the prevalence of PS in Alaska native people may be estimated as well. This registry will not only facilitate future research into PS etiology, but will also guide health care planning and community education efforts in this population. The proposal takes advantage of a case control study of PS that is commencing in the same population.

The registry is designed in two phases. Phase 1 is a developmental period that is currently ongoing. During this phase, data collection and dissemination protocols are being established, necessary approvals for the registry are being obtained, and a pilot project in Anchorage will be initiated following approvals. Phase 2 is a period of educational outreach and active statewide data collection on prevalent and incident cases of PS. After Phase 2 ends, the registry will be sustained through the Alaska Native Medical Center.

B. Body

The intent of this proposal is to establish a registry of parkinsonism cases among Alaska native people living in Alaska, documenting cases' clinical features and management. Our goal is to use this registry to shed light on the frequency and natural history of PS in this population, as well as to reduce the burden of disease for patients and caregivers by minimizing side effects of therapy, identifying and treating comorbid conditions, identifying currently undiagnosed cases of PS, and educating patients and care providers about optimal management of PS. To do this, the following milestones are being accomplished:

SCOPE OF WORK

Phase 1, Development and Pilot Study:

Task 1: Establishing the scientific steering committee.

Accomplishments:

The scientific steering committee was established. The members include Drs. Trimble, Tanner, Ferucci, and Ross. Dr. Gordon, originally on the scientific steering committee has since passed away.

Task 2: Developing an identification protocol. The primary source of PS cases will be the Indian Health Service (IHS) provider database, called the Resource and Patient Management System (RPMS), but the protocol will include identifying other possible sources that would identify other cases of parkinsonism among Alaska Natives.

Accomplishments:
We developed a protocol to search for approximately 30 ICD-9 codes within RPMS to identify any potential cases of PS. The protocol includes a method for electronically extracting the potential cases from RPMS to enable researchers to abstract available information from the RPMS database or paper charts for potential cases.

Task 3: Developing a secure Alaska Native PS registry database.
Accomplishments:
A contract was established with Peter Torkelson, owner of Advanced Design, to design our web-based database. Peter designed the Alaska Native Stroke registry database which is serving as a template for the Alaska Native Parkinsonism Registry (ANPR) database. Several phone calls and 1 face-to-face meeting were held with Peter to discuss issues unique to the ANPR and review the necessary data elements. We are currently working to refine the data flow on paper. Once this is complete, Peter will apply it to the web-based database.

Task 4: Ascertaining needs and interests of the Alaska Native community with regard to PS registry project.
Accomplishments:
This activity is ongoing in the Anchorage service area as we refine our pilot protocols and have face-to-face meetings in Anchorage. A total of 2 face-to-face meetings have occurred in Anchorage and 1 more is scheduled for December.

Task 5: Developing a preliminary proposal for review by Alaska Native tribal organizations. Subsequent more detailed versions of the protocol will be submitted for review as they are developed as well.
Accomplishments:
A detailed surveillance protocol was developed and is currently under review by the AK Area IRB and the privacy officer at the Alaska Native Tribal Health Consortium.

Task 6: Establishing appropriate infrastructure and personnel in Alaska.
Accomplishments:
We established contracts with 2 institutions, The Parkinson's Institute and the Pacific Health Research Institute, which will provide diagnostic expertise and project management services. Dr. Ferucci was brought on as a co-investigator for the registry project. She works at the AK Native Medical Center and the AK Native Tribal Health Consortium (ANTHC). She has identified several potential nurse coordinators and abstractors at ANTHC who may provide abstraction support. In an effort to conserve funds, we opted not to hire additional personnel while we are waiting for Regulatory approvals as this process can take extended periods of time.

Task 7: Developing detailed data collection and management procedures.
Accomplishments:
A method was developed for electronically extracting potential case data from RPMS to enable researchers to abstract necessary information from the RPMS database or paper charts for potential cases. A steering committee meeting is planned for

December 12, 2007 to further discuss data collection procedure. Registry personnel are currently working with Peter Torkelson to identify data management and reporting needs

Task 8: Developing detailed medical records abstraction protocols for data on clinical features, comorbid conditions, clinical management, and factors possibly affecting clinical management (e.g., home environment).
Accomplishments:
We are currently focused on obtaining human subjects approval to conduct the pilot phase of the study which is limited to disease surveillance in Anchorage. Following this pilot phase, we will begin focusing on Task 8 which will be part of a research protocol.

Task 9: Working with communities to develop a multilevel educational program for health care providers, patients, and caregivers, addressing PS identification and management.
Accomplishments:
Following the pilot phase, we will begin focusing on Task 9.

Task 10: Refining the study protocol and preparing the operations manual.
Accomplishments:
This work is ongoing as we incorporate feedback from regulatory entities and local experts. Additional refinements will occur following the conduct of the pilot in Anchorage.

Task 11: IRB approval and Alaska Native tribal organization feedback on and approvals of final protocols.
Accomplishments:
A detailed surveillance protocol for the pilot phase is currently under review by the AK Area IRB and the privacy officer at the Alaska Native Tribal Health Consortium.

Task 12: Pilot registry project among Alaska Natives residing in Anchorage Service Unit.
Accomplishments:
Task 12 activities are pending approval of the surveillance protocol that is currently under review by the AK Area IRB and the privacy officer at the Alaska Native Tribal Health Consortium.

Task 13: Initial implementation of educational program.
Accomplishments:
Following the pilot phase, we will begin focusing on Task 13.

Task 14: Monitor quality and completeness of registered data, and define data collection challenges.
Accomplishments:
This work has not been initiated. It will follow regulatory approval and data collection.

Phase 2, Registry Implementation:
When the tasks of the development phase have been completed, we will expand the collection of PS registry data to Alaska Natives statewide. The specific tasks for this phase will include:

1. Abstracting information from medical records of prevalent and incident PS cases into the PS registry.
2. Continuing implementation of educational program for health care providers, patients, and caregivers.
3. Reporting, analysis and publication.

C. Key Research Accomplishments

- Met with collaborating neurologists in AK, other local investigators, and Parkinson's Institute staff to develop potential methods of case ascertainment.
- Interactions with the Alaska Area IRB representatives and privacy officer to refine surveillance protocol.
- Submission of the surveillance protocol to the AK Area IRB and ANTHC privacy officer.
- Revisions to registry abstraction tool and protocols to satisfy the requests of the reviewers and the needs of the web-based database.

D. Reportable Outcomes

While many milestones of phase 1 of this project were met, we are still in the process of obtaining approvals necessary to begin data collection. Until this has been accomplished and state wide data has been collected, we will not have reportable outcomes.

E. Conclusions

Phase 1 of this project is well underway. We anticipate having the appropriate regulatory approvals and beginning data collection by early 2008. Following the completion of state wide data collection (Phase 1 and 2) and analysis, it will be possible to draw relevant scientific conclusions.

F. References

None

G. Appendices

A copy of the current abstraction tool is enclosed.

APPENDICES

ANPR ABSTRACTION FORM

PATIENT INFO
MEDICAL RECORD NUMBER:
FNAME:
LNAME:
DOB:
Address:
Phone:

ABSTRACTOR INFO
ABSTRACTED BY: O TRIMBLE O OTHER
ABSTRACTION DATE:

INFORMATION SOURCE(S) Select all that apply:
0 Medical records: 0 Neurologist 0 Non-Neurologist
0 Death certificate: _____(ICD code)

In view of all available information, what was the most likely age of onset?

CLINICAL SIGNS OR SYMPTOMS:

A. Parkinsonism

Resting tremor	O Yes O No O Questionable O DK
If Yes: present for at least 3 years?	O Yes O No O Questionable O DK
Rigidity	O Yes O No O Questionable O DK
If Yes: present for at least 3 years?	O Yes O No O Questionable O DK
cogwheeling?	O Yes O No O Questionable O DK
Bradykinesia	O Yes O No O Questionable O DK
If Yes: present for at least 3 years?	O Yes O No O Questionable O DK
Postural reflex impairment	O Yes O No O Questionable O DK
If Yes: present for at least 3 years?	O Yes O No O Questionable O DK

Asymmetric onset of parkinsonian signs O Yes O No O Questionable O DK O N/A

Was there a substantial and sustained response to levodopa or a dopamine agonist? O Yes O No O Questionable O Did not take O Inadequate trial O Unknown

***Other supportive features for Parkinson's disease**:* O Yes O No O Questionable O DK

a. stooped posture	0 Yes	0 No	0 Questionable	0 DK
b. decreased arm swing	0 Yes	0 No	0 Questionable	0 DK
c. shuffling gait	0 Yes	0 No	0 Questionable	0 DK
d. micrographia	0 Yes	0 No	0 Questionable	0 DK
e. diminished olfaction	0 Yes	0 No	0 Questionable	0 DK
f. seborrheic dermatitis	0 Yes	0 No	0 Questionable	0 DK

Exclusion criteria For PD:
O Prominent postural instability in the first 3 years
O Freezing in the first 3 years
O Hallucinations unrelated to medications in the first 3 years
O Dementia Preceding motor symptoms or in the first year
O Supranuclear gaze palsy other than restricted upward gaze or slowed vertical saccades
O Severe, symptomatic dysautonomia unrelated to medications.
O secondary cause of parkinsonism identified. If yes, specify

***Signs or symptoms suggestive of movement disorders additional or** alternative to **PD**:*
O Yes *Complete any appropriate sections that apply*
O No *SKIP to FINAL DISPOSITION*
O Questionable *Complete any appropriate sections that apply*
O DK *SKIP to FINAL DISPOSITION*

B. Features related to a diagnosis of DEMENTIA, esp. dementia with Lewy bodies

Cognitive impairment sufficient to interfere with normal social or occupational function:	O Yes	O No	O Questionable	O DK
Prominent memory type disturbance (for AIzheimer type dementia):	O Yes	O No	O Questionable	O DK
Fluctuating cognition with variation in attention and alertness:	O Yes	O No	O Questionable	O DK
Visual hallucinations	O Yes	O No	O Questionable	O DK

***Other supportive features for DLB**:* O Yes O No O Questionable O DK (If yes or questionable indicate all that apply)

O Repeated falls
O Transient loss of consciousness
O Neuroleptic sensitivity
O Systematized delusions
O Hallucinations in other modalities

C. Features related to a diagnosis of PROGRESSIVE SUPRANUCLEAR PALSY

Gradually progressive disorder	O Yes	O No	O Questionable	O DK
Vertical supranuclear gaze palsy	O Yes	O No	O Questionable	O DK
Fails within first year of onset	O Yes	O No	O Questionable	O DK
Onset age 40 or later	O Yes	O No	O DK	

Other supportive features for PSP O Yes O No O Questionable O DK (*IF Yes or **Questionable indicate** all that apply)*

O Symmetric akinesia or rigidity, proximal more than distal
O Abnormal neck posture,esp, retrocollis
O Poor or absent response to levodopa
O Early dysphagia and dysarthda
O Eady cognitive impairment consistent with PSP (apathy, impaired distraction,signs of frontal lobe dysfunction)

D. Features related to a diagnosis of MULTIPLE SYSTEM ATROPHY

Autonomic dysfunction	O Yes	O No	O Questionable
Cerebellar dysfunction including gait ataxia	O Yes	O No	O Questionable
Symptom onset after age 30	O Yes	O No	O DK

E. Features related to a diagnosis of CORTICOBASAL DEGENERATION

Sign(s) of cortical dysfunction	O Yes	O No	O Questionable	O DK
Asymmetric dgidity	O Yes	O No	O Questionable	O DK
Asymmetric dystonia	O Yes	O No	O Questionable	O DK
Focal reflex myoclonus	O Yes	O No	O Questionable	O DK

F. Features related to a diagnosis of ESSENTIAL TREMOR

Postural or kinetic tremor O Yes O Questionable O DK

***Characterize tremor**:* **a**. O Arms O Bilateral O Unilateral O Postural O Kinetic
O Legs O Bilateral O Unilateral O Postural O Kinetic
O Voice
O Chin
O Head
O Tongue
O Other (specify):

b. O Isolated task-specific tremor O Isolated position-specific tremor

Exclusionary/Modifying criteria for ET:

Any condition that might cause tremor? O Yes O No ODK
If Yes: O PD O Dystonia O Other(specify)
Was onset AFTER onset of postural or kinetic tremor?
O Yes O No ODK
Exposure to tremorgenic medication: O Yes O No ODK If Yes, specify:
Other unequivically abnormal
signs precluding diagnosis of ET: O Yes O No ODK
If Yes: 0 parkinsonism 0 other (specify):
Equivocal neurologic signs of doubtful significance O Yes O No ODK If Yes, specify:
Rate most severe postural or kinetic tremor: 0 I 0 2 0 3 0 4

FINAL DISPOSITION: DIAGNOSIS LIST

Indicate all that apply.

O NO NEUROLOGIC DISEASE

PARKINSON'S DISEASE

	by Gelb	byCAPIT
Definite Parkinson's disease	O	
Probable Parkinson's disease	O	O
Possible Parkinson's disease	O	O

O Likely Parkinson's disease but insufficient information to fulfill diagnostic cdterie

SECONDARY PARKINSONISM, DUE TO

O Dopamine receptor blocking or dopamine depleting drugs O Toxicant induced, other *(specify cause below):*
O Vascular
O Other secondary *parkinsonism (specify cause below)*

DYSTONIA

O Primary generalized dystonia
O Focal dystonia *(Specify region):* *I*
O Other dystonia *(Specify diagnosis below):*

PARKINSONISM PLUS SYNDROMES

(If applicable, indicate any subclassification below in the comments box)

O Progressive supranuclear palsy
O Olivopontocerebellar Atrophy
O Multiple Systems Atrophy parkinsonism
O Cortical-Basal-Ganglionic Degeneration
O Multiple Systems Atrophy cerebellar
O Other Parkinsonism Plus Syndrome (Specify diagnosis)

DEMENTIA

O Dementia with Lewy bodies (DLB)
O Alzheimer's-like dementia with parkinsonism
O Alzheimer's-like dementia without parkinsonism
O Other dementia *(specify):I*

ESSENTIAL TREMOR

Modified TRIG		TRIG 2000	
Definite	O	Classic	O
Probable	O	Indeterminate	O
Possible	O	Possible:	
Questionable	O	Type I	O
Not Essential Tremor	O	Type I, temporalify unknown	O
		Type II	O
		Not Essential Tremor	O

OTHER NEUROLOGIC DISEASE

O Other neurological disease *(specify diagnosis below)*

Do you suspect that this person may have early PD even if he/she does not fulfill diagnostic criteria for parkinsonism?
O Yes O No ON/A

Comments? O Yes O No Comments